Which attributes of LA-ART will affect acceptability?

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Disclosures

• R01 Grant from National Institute of Health
• Discussing the use of drugs that are in the pipeline and not FDA approved
**Targeted Long-Acting Combination ART (TLC-ART) Program**
NIH UM1 AI120176 (co-PIs Ho, Collier)

- **Goal:** To facilitate and guide development of 3 safe, stable, scalable and well-tolerated LA ART formulations for Phase 1 clinical trials

- **Innovative aspects:**
  - Focus on developing a complete **multidrug** regimen for parenteral delivery
  - Targeting of lymphoid tissues using drug-lipid nano-formulations that can be administered **subcutaneously**
Acceptability Research (Lead, Simoni)

• Recruitment of providers, PLWH, and parents of infected children from 3 HIV clinics in Seattle and rural southern California

• Qualitative interviews and focus group discussions
  • Notes taken, recordings transcribed
  • Content analysis with coding of salient themes

• Conjoint analysis used to
  • Estimate consumer preferences across discrete attributes
  • Identify factors associated with acceptability
Qualitative FGD and IDI

• Six FGDs conducted with experienced HIV care providers (n=7) and PLWH (n=36)
• IDIs conducted with parents of children living with HIV (n=5)
• Providers predicted enthusiasm, especially from patients with adherence challenges, but were concerned about the potential for negative impact on care engagement
• Parents’ interest varied according to their child’s age and sensitivity to injections
Qualitative Findings, PLWH

• Concept of long acting injectable ART acceptable despite some concern ("trigger" for IDU)
• Most PLWH preferred clinic administration over self-injection
• Concerns about possible side effects, additional costs, effectiveness compared to oral meds
• Moderate injection site pain more acceptable than multiple injections
• Minimal dosing interval 2 weeks, although 1 month preferred
Conjoint Analysis Methods

• 56 PLWH aged ≥18 (median age 52 years, 72% male, 36% Black, 20% Hispanic)

• 8 hypothetical long-acting injectable ART drug profiles varying across 6 dichotomous attributes based on qualitative findings:
  • Location (home vs. clinic)
  • Frequency (qweek vs. q2week)
  • Dose (1 vs. 2 injections)
  • Pain (mild vs. moderate)
  • Injection site reaction (mild vs. moderate)
  • Effectiveness (as good vs. better than pills)

• Participant rated likelihood to use each profile: 0=highly unlikely, 25=somewhat unlikely, 50=neutral, 75=somewhat likely, 100=highly likely
Conjoint Analysis Results

Table 1. Conjoint Analysis of Acceptability of Long-Acting Injectable ART among Key populations in the U.S. (N=56)

<table>
<thead>
<tr>
<th>Acceptability Scores (Overall: 57.87)</th>
<th>Attributes [Preferred underlined in italics]</th>
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</thead>
<tbody>
<tr>
<td>Location</td>
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<td>47.78</td>
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<tr>
<td>Impact Score (p-value)</td>
<td>-5.02 (0.42)</td>
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</tbody>
</table>
Focus Groups in Kenya

• 6 focus groups of PLWH
  • General population men and women, male and female adolescents, female sex workers (FSW), men who have sex with men (MSM)

• Main themes:
  o Poor adherence in the context of high stigma and many side effects – led to high enthusiasm about an injectable option
  o Most had no access to refrigeration
  o Non-disclosure and stigma led to concerns about storage
  o Injections site – NOT stomach
  o Pain not an issue, accustomed to getting injections
  o Getting two shots for one dose not an issue
  o Preferred not to have to come to clinic because of distance, cost, and insensitive treatment
  o Having needles, site reactions feared due to potential stigma
Figure 1. Factors Associated with the Acceptability of LA-ART Products

Sociocultural/Policy
- Funding, policy adoption, health policy

Institutional/Community
- Service provision factors, "friendly" services, LA-ART information provision, community HIV stigma

Inter-personal
- Relationship with providers; social support; stigma/disclosure

Intra-personal
- Age, sex, socioeconomic status, personal history, HIV history, beliefs/values, transportation costs, opportunity costs

Product Attributes
- Dose, route of administration, frequency, side effects, cost

Delivery Attributes
- Location provided, need for trained personnel, wait times, procedures

Access to LA-ART
- Insurance coverage, formulary status, financial constraints

Information on LA-ART
- Drug development stage, FDA approval status, clinical trial results

Behavioral Skills
- Appointment-keeping, planning skills, problem-solving skills, self-injection skills (if applicable)

Motivation for LA-ART Use
- Belief in LA-ART, preference for LA-ART, experience with oral regimens

LA-ART Use
- Uptake
- Adherence
- Persistence
Questions

• What are the product and delivery attributes that would facilitate uptake, adherence, and persistence on LA-ART regimens among end-user populations?

• How best to measure acceptability as products are in development? Simulated delivery needed?

• How much will end-user views and delivery challenges differ across regions? Across populations?